4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0492]

Watson Laboratories, Inc., et al.; Withdrawal of Approval of 36 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 36 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 062142	Doxycycline Hyclate Capsules, Equivalent to (EQ) 50 milligrams (mg) base and EQ 200 mg base	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054
ANDA 062497	Doxycycline Hyclate Capsules, EQ 50 mg base and EQ 100 mg base	Teva Pharmaceuticals USA, Inc., 400 Interpace Pkwy., Building A, Parsippany, NJ 07054
ANDA 065152	Cephalexin Capsules, EQ 250 mg base and EQ 500 mg base	Yung Shin Pharmaceutical Ind. Co. Ltd., authorized U.S. agent, Carlsbad Technology, Inc./Simon Law, 5922 Farnsworth Ct., Suite 101, Carlsbad, CA 92008
ANDA 070550	Propranolol Hydrochloride (HCl) Tablets, 40 mg	Watson Laboratories, Inc.
ANDA 070551	Propranolol HCl Tablets, 80 mg	Do.
ANDA 070943	Oxazepam Capsules, 10 mg	IVAX Pharmaceuticals Inc. (an indirect wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054
ANDA 070945	Oxazepam Capsules, 30 mg	Do.
ANDA 071446	Temazepam Capsules, 15 mg	Watson Laboratories, Inc.
ANDA 071447	Temazepam Capsules, 30 mg	Do.
ANDA 072952	Oxazepam Capsules, 10 mg	Do.
ANDA 073092	Baclofen Tablets, 10 mg	Do.
ANDA 074400	Diflunisal Tablets, 250 mg and 500 mg	Do.
ANDA 074432	Diclofenac Sodium Delayed Release Tablets, 50 mg and 75 mg	Pliva, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054
ANDA 074460	Piroxicam Capsules, 10 mg and 20 mg	Watson Laboratories, Inc.
ANDA 074585	Indapamide Tablets, 1.25 mg and 2.5 mg	Do.
ANDA 074698	Baclofen Tablets, 10 mg and 20 mg	Do.
ANDA 074711	Mexiletine HCl Capsules, 150 mg, 200 mg and 250 mg	Do.
ANDA 074723	Diclofenac Sodium Delayed Release Tablets, 50 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074852	Diltiazem HCl Extended Release Capsules, 120 mg, 180 mg, and	Actavis Laboratories FL, Inc. (an indirect, wholly owned subsidiary

	240 mg	of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054
ANDA 074865	Mexiletine HCl Capsules, 150 mg, 200 mg, and 250 mg	Watson Laboratories, Inc.
ANDA 074870	Acyclovir Tablets, 400 mg and 800 mg	Actavis Elizabeth LLC (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054
ANDA 075101	Acyclovir Capsules, 200 mg	Watson Laboratories, Inc.
ANDA 076022	Fluoxetine HCl Capsules, EQ 10 mg base and EQ 20 mg base	Carlsbad Technology, Inc., 5922 Farnsworth Ct., Carlsbad, CA 92008
ANDA 078345	Prednisolone Sodium Phosphate Solution, EQ 15 mg base/5 milliliters (mL)	Amneal Pharmaceuticals, 85 Adams Ave., Hauppauge, NY 11788
ANDA 080521	Isoniazid Tablets, 300 mg	Watson Laboratories, Inc.
ANDA 086537	Nitroglycerin Controlled-Release Capsules, 6.5 mg	Lumara Health, Inc., 1100 Winter St., Suite 3000, Waltham, MA 02451
ANDA 086889	Disulfiram Tablets, 250 mg	Watson Laboratories, Inc.
ANDA 086890	Disulfiram Tablets, 500 mg	Watson Laboratories, Inc.
ANDA 087975	Nitroglycerin Controlled-Release Capsules, 2.5 mg	Sandoz Inc., 100 College Rd. West, Princeton, NJ 08540
ANDA 087976	Nitroglycerin Controlled-Release Capsules, 6.5 mg	Do.
ANDA 088509	Nitroglycerin Controlled-Release Capsules, 9 mg	Do.
ANDA 090833	Carbidopa/Levodopa and Entacapone Tablets, 18.75 mg/200 mg/75 mg, 25 mg/200 mg/100 mg, 31.25 mg/200 mg/125 mg, 37.5 mg/200 mg/150 mg, and 50 mg/200 mg/200 mg	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC., 6451 Main St., Morton Grove, IL 60053
ANDA 200771	Irinotecan HCl Injection, 40 mg/2 mL (20 mg/mL) and 100 mg/ 5 mL (20 mg/mL)	Heritage Pharmaceuticals Inc. d/b/a/ Avet Pharmaceuticals Inc. U.S. Agent for Emcure Pharmaceuticals Limited, One Tower Center Blvd., East Brunswick, NJ 08816
ANDA 202063	Gemcitabine HCl for Injection, EQ 200 mg base/vial; EQ 1 gram base/vial	Do.
ANDA 204437	Sodium Fluoride 18 Injection, 10-200 millicurie (mCi)/mL	UCSF Radiopharmaceutical Facility, 185 Berry St., Suite 350, San Francisco, CA 94107
ANDA 208444	Choline C-11 Injection, 4-33.1	Do.

	mCi/mL	

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: June 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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